REMARKS

This is in response to the Official Action of July 28, 2004, and the Interview among Examiner Frank Choi, Dr. Shankar Gupta, Dr. Barry Maurer, and Mr. Kenneth Sibley of September 26, 2005.

During the interview and as discussed further below, Dr. Gupta discussed the challenges encountered in developing this particular formulation, and Dr. Maurer discussed the need for this particular formulation in pediatric oncology, particularly in light of the prior unsatisfactory formulations available for administration of fenretinide. The rejections of record were then discussed and preliminary agreement was reached on amendments to the claims to resolve the outstanding rejections, as discussed further below.

The specification has been amended above to indicate that the reference cited on Pg. 10, lines 13, 14, is now US Patent No. 6,368,831.

Enablement.

Claims 18, 19 and 22 stand rejected under 35 USC 112, first paragraph, as lacking enablement for egg phospholipids as nonionic surfactants. Mr. Sibley commented that these claims were being kept of record until the "new matter" rejection (discussed below) was resolved one way or the other. The "new matter" rejection having been resolved as discussed below, claims 11-28 have been cancelled. Accordingly it is submitted that this rejection is now moot and may be withdrawn.

Written Description.

Claims 29-37 stand rejected as lacking written description for the term "egg phospholipids" in the context of being non-ionic. During the interview, Dr. Maurer and Dr. Gupta discussed the neutral charge on this molecule in the formulations of the invention, and Mr. Sibley emphasized that the inventors were in possession of "egg phospholipids" as their surfactant as of the filing of this application. Examiner Choi pointed out that the usage of "egg phospholipid" without ionic or non-ionic qualification in Example 2, page 11, provided support for the term "egg phospholipids" and that this would be accepted as a basis for written description of this term in the claims. Claim 29 having been so amended above, it is respectfully submitted that this rejection should now be withdrawn.

Obviousness.

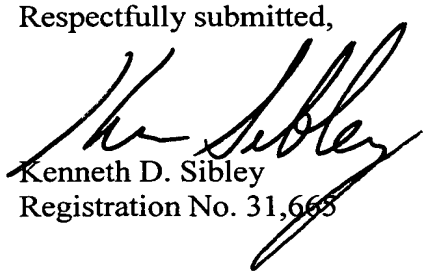
Claims 11-41 stand rejected as obvious under 35 USC 103(a) over **Lopez-Berestein** et al. in view of **Chen** et al., **Lambert** et al. and **Shudo** et al.

During the interview, Dr. Gupta discussed the difficulties in developing a poorly water soluble drug like fenretinide as an emulsion formulation without excessive inclusion of alcohol, and with an appropriate particle size for delivery. Dr. Maurer emphasized the need for an emulsion formulation of fenretinide for parenteral delivery due to the unsatisfactory dosages obtainable with prior oral formulations of fenretinide, the satisfactory results obtained to date with the present formulation in pediatric cancer patients, and also the advantage of utilizing soybean oil as the lipid in the instant formulation due to its nutritive value. Examiner Chen indicated that claim 29, if directed to soybean oil as the lipid, ethanol as the solvent, egg phospholipid as the surfactant, and glycerin in a range of 1 to 10 as the isotonic agent, should obviate the outstanding obviousness rejection under 35 USC 103.

Claim 29 has been so amended above. Claims 11-28 have been cancelled. Other claims have been cancelled as now repetitive, or amended to insure that all remaining claims depend upon claim 29. Accordingly, it is respectfully submitted that this rejection is now obviated, and that this rejection should be withdrawn.

It is respectfully submitted that this application is in condition for allowance, which action is respectfully requested.

Respectfully submitted,



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